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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,385	05/11/2007	Joseph J. Barchi	NIHA-0278	1844
45160	7590	05/19/2011		
OTT- NIH c/o WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891			EXAMINER HARRIS, ALANA M	
			ART UNIT 1643	PAPER NUMBER
			NOTIFICATION DATE 05/19/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

coffice@woodcock.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/578,385	<b>Applicant(s)</b> BARCHI ET AL.	
	<b>Examiner</b> Alana M. Harris, Ph.D.	<b>Art Unit</b> 1643	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-41 and 43-76 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 15-41, 70 and 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-47, 50-53, 55-59, 63, 65-69 and 72-75 is/are rejected.
- 7) ☒ Claim(s) 48, 49, 54, 60-62, 64 and 76 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/26/2008</u>  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group II (claims 43-69 and 71-76) in the reply filed on May 7, 2009 is acknowledged. Foremost, the Examiner inadvertently placed claims 70 and 71 that are dependent on withdrawn claim 1 with the elected Group. The Examiner notes non-elected Group I consists of claims 1-13, 15-41, 70 and 71. The Examiner apologizes for the error.

The traversal is on the ground(s) that the Examiner has not shown the two criteria for a proper requirement according to MPEP 803. This is not found persuasive because as noted in the Requirement mailed February 12, 2010, the two method Groups are patentably distinct and different because they differ in reagents, method steps and method endpoints. These two different processes are separable and would be classified in different groups and subgroups.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-13, 15-41 and 43-76 are pending.

Claims 14, 42 and 77-79 have been cancelled.

Claims 1-13, 15-41, 70 and 71, drawn to non-elected inventions are withdrawn from examination.

Claims 43-69 and 72-76 are examined on the merits.

***Claim Objections***

3. Claims 43 and 51 are objected to because of the following informality: they both cite GM3, however Applicants should select which citing, either GM<sub>3</sub> or GM3 for continuity of claims. Correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 50 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 50 cites "...the immune system..." on line 2. However, claim 43 lacks antecedent bases for the recitation.

b. Claims 70 and 71 cite "...the molecular weights..." on line 1. However, claim 1 lacks antecedent bases for the recitation.

***Claim Rejections – 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 43-47, 50-59, 63, 65-69 and 72-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragupathi et al. (Cancer Immunol. Immunother. 48: 1-8, 1999/ IDS reference number 11 submitted February 26, 2008), and further in view of Lloyd, K.O. (Drug News. Perspect. 13(8): 463-470, October 2000/ IDS reference 12 submitted February 26, 2006), WO document, WO 02/32404 A2 (published 25 April 2002), and Otsuka et al. (J. Am. Chem. Soc. 123: 8226-8230, 2001/ IDS reference 7 submitted February 26, 2008). Ragupathi teaches the administration of vaccines comprising sialyl-Tn or clustered STn [STn(c)]-keyhole limpet hemocyanin (KLH) conjugates linked with 4-(4-maleimidomethyl)cyclohexane-1-carboxyl hydrazide (MMCCH) linkers to mice and LS-C human colon cancer cells, see Abstract on page 1; and page 2, "Vaccine..." and "Animals..." sections. Ragupathi does not teach the said plurality of Tn antigens (expressed on colon and prostate tumors) with additional carbohydrate antigens, such as fucosyl GM1 antigen, T-F and Lewis Y antigen in a nanoparticle or administered to a human.

Lloyd teaches different carbohydrate antigens, GM1 (expressed on small-cell lung cancer), Lewis Y (expressed on tumors of lung and prostate), T-F (expressed on tumors of breast and prostate) can be administered to subjects in vaccine formulations, see the entire reference. Lloyd also teaches epitopes can exist on the cell surface, see page 464, 2<sup>nd</sup> column. The WO document teaches nanoparticles comprising carbohydrate groups and implementation in therapy and medical treatment including inhibiting metastasis of cancer, see abstract; page 4, lines 4-14; page 12, lines 14-23; and page 14, lines 15-28. The nanoparticles of the antigen-nanoparticles conjugates have one or more carbohydrate groups, the mean diameter between 0.5 and 100nm, 100 to 500 gold atoms, see page 4, line 31-page 5, line 17; and page 7, lines 1-25. Otsuka teaches PEGylated gold nanoparticles comprising a gold-thiol linkage produced after chemical reduction with  $\text{NaBH}_4$ . It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of all references to combine a plurality of target carbohydrate cancer antigens as an immunogenic polyvalent antitumor vaccine, see all documents in their entirety. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in all the references, that an antigen-nanoparticle formulation would be effective in producing antibodies that are capable of reacting with tumor cells and ultimately destroying tumors that express these antigens.

***Allowable Subject Matter***

8. Claims 48, 49, 60-62, 64 and 76 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a ***flexible schedule***, however she can normally be reached Monday through Friday, 8 am to 8 pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Misook Yu, Ph.D. can be reached on (571)272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.  
02 August 2010  
/Alana M. Harris, Ph.D./  
Primary Examiner, Art Unit 1643